K013500

SECTION 9

510(k) SUMMARY

JAN 1 4 2002

This 510(k) summary of safety and effectiveness for PolyLUX II is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: KaVo America

Address: 340 East Main Street
Lake Zurich, IL 60045

Manufacturer: KaVo Dental GmbH
Bahnhofstr. 20
D-8847 Warthausen
Biberach
GERMANY

Contact Person: Ms. Jennifer Pottala

Telephone: 847-550-6800
847-550-6825 (Fax)
800-323-8029

Preparation Date: August 2001
(of the Summary)

Device Name: PolyLUX II

Common Name: Dental Curing Light

Classification: Activator, Ultraviolet, for Polymerization (Class II medical device; (21 CFR 872.6070).

Product Code: EBS
Panel: 76

Predicate devices: VIP-Variable Intensity Polymerizer (Bisco, Inc.), Elipar FreeLight and TriLight (ESPE Dental AG), Versalux (Centrix, Inc.), Palmlight; Optilux; Avanté (Jeneric/Pentron, Inc.), and Coltolux 3 and 4 (Coltene/Whaledent AG).

Note: In searching company web sites the particular model curing lights cited in the 510(k) data base were not always found but comparable [perhaps] models were noted.

Device description: PolyLUX II is a hand piece with a halogen quartz light source intended for curing dental resins.

Indications: PolyLUX II is a hand piece for polymerization and is intended exclusively for dental treatment in regular dentistry.

KaVo proposes that the PolyLUX II be labeled:

"CAUTION: Federal (US) law restricts the use of this device to licensed professionals."

Performance Data: None required. The claim of substantial equivalence is based on comparisons of formulations and intended uses of the claimed predicate.

CONCLUSION: Based on the information in the notification KaVo America believes that PolyLUX II is substantially equivalent to the claimed predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 4 2002

Ms. Jennifer Pottala
Kavo America
340 East Main Street
Lake Zurich, Illinois 60047

Re: K013500
Trade/Device Name: KaVo PolyLux II
Regulation Number: 872.6070
Regulation Name: Activator, Ultraviolet, For Polymerizations
Regulatory Class: II
Product Code: EBZ
Dated: October 22, 2001
Received: October 22, 2001

Dear Ms. Pottala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K013500

Device Name: KaVo PolyLUX II

Indications for Use Statement:

KaVo PolyLUX II is a handpiece for polymerization and is intended exclusively for dental treatment in regular dentistry.

KaVo proposes that KaVo PolyLUX II carry the following label:

CAUTION: Federal (US) law restricts the use of this device to licensed professionals.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The Counter Use ___
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013500